Without PBM Reform and an IRA Fix, Drug Shortages Are Inevitable

By Ted Love
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When Intas Pharmaceuticals, an Indian generic manufacturer, was forced to shut down its production line, the United States lost nearly half its supply of two of the most widely used chemotherapy treatments. Suddenly, patients with breast, cervical, bladder, testicular, and other cancers faced hastily crafted rationing plans.

Right now, nearly 250 generic drugs are in critically short supply. These drugs range from cancer treatments to antibiotics to drugs that treat ADHD or irregular heartbeats.

To end this crisis -- and prevent it from worsening -- we must fix the structural issues that have long burdened the generic drug market. And we must also address the little-known new burdens that last year's Inflation Reduction Act have placed on generic manufacturing -- and the substantial risk of IRA-induced brand-name shortages, as well.

Let's begin with how the market currently works. Since the 1960s, pharmacy benefit managers, or PBMs, have served as middlemen between drug manufacturers and the pharmacies where patients fill prescriptions. That includes both brand-name and generic drugs.

As the PBMs prospered with the boom in prescription drug spending, consolidation occurred, leaving 3 companies -- CVS Caremark, Optum Rx, and Express Scripts -- with 80% of the prescription drug market. Nine in ten prescriptions are filled with generics.

This market dominance provides the PBMs enormous buying power. They use it to demand steep discounts from manufacturers for favorable inclusion of their products on insurance policy formularies. This ability to extract discounts works especially well with generic manufacturers and brand-name drugs with one or more generic competitors.

With PBMs driving hard bargains on price, production of generics migrates toward manufacturers who can deliver the goods at the lowest cost. Those who can't compete go out of business. Over time, prices get pushed lower and lower, and margins are compressed further until only a few remain -- perhaps one or two.

That's when shortages start. A sudden demand increase, natural disaster, or corporate mismanagement can lead to an immediate shortage, with no other drug makers able to fill the gap.

The IRA is about to inflict collateral damage on the generic drug market similar to that introduced by the rising buying power of PBMs. Medicare, which accounts for 30% of domestic prescription drug spending, will begin setting price ceilings on certain widely used brand-name drugs.

What does controlling prices on brand-name drugs have to do with generic production? Very simply, the delta between the price of manufacturing a pill and the price one can charge on the marketplace for a brand-name medicine constitutes the incentive for companies to go into the business of making generics. Generic drug manufacturers move in to offer an equivalent product at a lower price, which generally also forces the price of the name-brand down as well.

With Medicare imposing price controls on brand-name drugs that are still protected by patents, the government is effectively capturing much of the spread between the production cost and the market price. So suddenly, the incentive for a generic company to enter the marketplace is gone.

The point here is two-fold. Before the dramatic rise of the buying power of PBMs, drug shortages were fewer because enough generic manufacturers could stay profitable to overcome disruptions on the supply or demand side. That's no longer true.

And the problem may soon extend to brand-name drugs, whose patents may expire without a competitor entering the market. This problem won't be limited to drugs under price controls, but any drug that might be subject to them down the line. The very possibility of price controls will keep generic manufacturers out. And brand-name drug makers will have limited incentive, due to price controls, to foot the bill to maintain excess capacity.

The reality of PBM consolidation and IRA price controls is that when coercive power -- whether from market position or government fiat -- keeps prices down, shortages emerge. Until this is fixed, more shortages are inevitable.

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